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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,271	08/22/2003	Jay D. Caplan	0010.0006	9460
29127	7590	02/12/2007	EXAMINER	
HOUSTON ELISEEVA 4 MILITIA DRIVE, SUITE 4 LEXINGTON, MA 02421			ROZANSKI, MICHAEL T	
			ART UNIT	PAPER NUMBER
			3768	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/646,271	Applicant(s) CAPLAN ET AL.
	Examiner Michael Rozanski	Art Unit 3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 August 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-64 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-64 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 22 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
:8/25/03,3/12/04,1/13/05,3/24/06.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-73 of copending Application No. 10/426,750. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application substantially claims all features of the current invention including a method for analyzing blood vessels in the presence of intervening fluid comprising irradiating vessel walls with an optical source, collecting spectral responses, determining spectral responses of the vessel walls from the collected responses, and generating information for the

assessment of vessel walls (i.e. diagnosis) in response to the determined spectral response of vessel walls. The spectral response of blood samples may be taken from the patient and may, subsequently, be compared to known spectral features of blood. Furthermore, the method includes analysis of the signal comprising algebraic analysis and chemometric analysis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-6, 11-13, 19-21, 23-33, 39-41, 47, 48, and 50-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Auer et al (US Patent No. 5,383,467).

Claims 1-6, 11-13, 19-21, 23-33, 39-41, 47, 48, and 50-64: Auer et al. disclose an optical catheter 15, and the use of an interferometer for analysis (col. 1, lines 6-11). At the distal end 27 of catheter 15, a coil is formed that has an outer diameter of 0.014

inches and a lens 58 are present, and could function as fins of the main catheter body (col. 5, lines 27-49). The catheter is positioned within a blood vessel 26, which is illuminated by a light source capable of operating at several wavelength simultaneously (col. 5, lines 9-14), wherein a beam of reflected energy is returned from tissue mass 28 by operation of catheter and fiber coupler 18 (col. 4, lines 41-43). Signal data from the photodetector 31 and signal detector 24 provides input to the computer 21, which includes a display output 35 whereat the X-Y plane configuration of vessel 26 is displayed and a determination of when the probe is close enough to vessel wall may be made (col. 4, lines 41-61). The amplitude of the interference signal is plotted as the Y coordinate, wherein a threshold could be set at a specific amplitude, and as a variable function of the X position of the catheter's distal end 27 within the vessel (col. 4, lines 41-61). The spikes in the signal plot represent discontinuities in the tissue mass 28 and the average slope of the signal plot between adjacent spikes represent the average extinction coefficient for the tissue mass (col. 4, lines 62-68).

4. Claims 53-58 are rejected under 35 U.S.C. 102(b) as being anticipated by

McGee et al (US Patent No. 5,752,518).

Claims 53-58: McGee et al. disclose a catheter tube with a motor 58 that rotates the transducer crystal 52, thereby inducing movement between the probe head and the vessel walls (col. 7, lines 1-4). The distal end 220 includes an outer sheath 226 that extends into the distal body region 225 may be used as a fin for interaction with flowing blood and catheter navigation (col. 8, lines 18-22; figure 25). Furthermore, the system

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includes a gating circuit 190 for acquiring images by using the QRS of an electrocardiogram (col. 10, lines 59-63).

5. Claims 1-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Marshik-Geurts et al (US 2004/0024298).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-64: Marshik-Geurts et al. disclose an optical spectroscopic catheter system 50 for use in a blood vessel that is capable of performing all claimed functions of the claimed method including receiving optical signals from vessel walls through intervening blood, analyzing the signals using quantitative or qualitative analysis to determine whether probe is close enough to the vessel wall, and using the signals to diagnose the vessel walls (para. [0012], [0055]). Specifically, the analyzer 42 is used to discriminate classification group from all other spectra features in the presence of intervening fluid and may quantify the presence of one or more chemical constituents that comprise the spectral signatures of a normal or diseased blood vessel wall (para. [0068]-[0069]; figure 2). The analyzer preprocesses the collected spectra, which

emphasizes the response of the vessel walls relative to the response of the unwanted spectral signals, such as that of the intervening fluid (para. [0070]).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR
MR

Eleni Mantis
ELENI MANTIS-MERCADER
SUPERVISOR, PATENT EXAMINER

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